

REMARKS

Status of the Claims

Claims 90-96, 98-126, 128-167, 173 and 174 are currently pending in the subject application. By this amendment, Claims 90, 95, 98-100, 108-110, 120, 121, 158 and 163-167 have been amended without prejudice or disclaimer, and Claims 175-215 have been added to define the invention in another form and includes the feature that the overflow chamber is disposed between the pump and the holding chamber. Thus, upon entry of this Amendment, Claims 90-96, 98-126, 128-167, and 173-215 will be pending in the subject application.

Claims 90 and 167 have been amended to place language from the preamble into the body of the respective claims. Claims 90, 95, 98-100, 109-110, 120, 121, 158 and 163-167 have been amended to address minor typographical errors and to ensure proper antecedent basis. Claim 108 has been amended to place it in a form similar to Claim 119 as suggested by the Office. Claim 110 has been amended to modify the claimed range to reflect the range recited at page 15, lines 22-24, of the specification. No new matter has been added.

January 30, 2009 Examiner Interview

Applicants would like to thank Examiner Alexander for the personal interview conducted on January 30, 2009. In compliance with M.P.E.P. § 713.04, the substance of that interview is reflected in the January 30, 2009 Interview Summary and in the following remarks.

In the interview, the rejection under 35 U.S.C. §112, first paragraph, was discussed, and the Office tentatively agreed that FIGS. 2 and 5 from the original specification teach the claimed configuration of an overflow chamber disposed between the pump and the holding chamber. The Office agreed to vacate this rejection in the next communication. Applicants' representative also argued that the cited art fails to pump air through an overflow chamber. Instead, the Handique et al. patent teaches the displacement of a metered sample "L" while *bypassing* the overflow region (30). (Handique at FIGS. 3A, 3B). Handique does not teach or suggest air flowing through an overflow chamber. In response to this argument, the Office agreed to vacate the rejection under 35 USC §102(b) in the next communication. The remaining issues of alleged

obviousness type double patenting and the 35 USC §112, second paragraph, rejections are addressed in this Response as discussed in the interview. Finally, it was indicated that when Applicant's representative addresses these outstanding issues in this Response, the Office would formally vacate the above indicated rejections.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 90-96, 98-126, 128-167 and 173-174 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

As discussed and agreed to in the Examiner Interview, FIGS. 2 and 5 and the corresponding text of the subject application clearly illustrate and describe an overflow chamber disposed between the pump and the holding chamber. (See, e.g., p. 17, line 24, to p. 19, line 5.) Accordingly, one skilled in the art would readily appreciate that Applicants were in possession of the claimed invention at the time of filing. The withdrawal of this rejection is accordingly requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 90-96, 98-126, 128-167 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended Claim 90 to move the indicated language to the body of the claim, and it is solicited that this rejection has been thereby obviated. Applicants thus request the withdrawal of this rejection.

The Office Action also indicated that the claims do not specify the flow of the sample from the pump, through the overflow chamber and ultimately in the holding chamber. (O/A at p. 3). As a result, the Office assumed for purposes of examination that the sample flows from the pump to the overflow chamber and finally to the holding chamber. (O/A at p. 3). As a point of clarification, while a portion of the sample may be introduced into the overflow chamber in order to form a metered sample in the holding chamber, the metered sample itself flows from the holding chamber to the analysis location. Thus, the metered sample does not flow from the pump to the overflow chamber and finally to the holding chamber.

Claim 108 has been rejected as allegedly failing to further limit the method of Claim 90. The Office recommended incorporating similar amendments that previously were made to Claim 119. (O/A at p. 3). Although Applicants disagree with the contention that Claim 108 does not further limit Claim 90, Applicants have amended Claim 108 in a manner similar to Claim 119 in order to expedite prosecution. Accordingly, the withdrawal of this rejection is requested.

Double Patenting

Claims 90-96, 98-126, 128-167 and 173-174 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-107 and Claims 1-47 of U.S. Patent Nos. 6,750,053 and 6,438,498, respectively. Applicants submit herewith a terminal disclaimer with respect to the ‘053 and ‘498 patents thereby rendering this rejection moot. Applicants request the withdrawal of this rejection.

Rejection Under 35 U.S.C. §§102(b)

Claims 173-174 stands rejected under 35 U.S.C. §102(b) as being anticipated by Handique et al. (USP 6,103,098). Applicants respectfully traverse this rejection.

The invention of pending Claim 173 is a method of detecting a reaction product in a sample of blood or blood derivative using a cartridge that includes a holding chamber, an overflow chamber, an analysis location, a pump, a reagent and a sensor. The method comprises the steps of (a) introducing the sample into the holding chamber in the cartridge; (b) metering a portion of the sample in the holding chamber by retaining excess sample in the overflow chamber; (c) moving the metered sample from the holding chamber to the analysis location by pumping air with the pump *through the overflow chamber* to the metered sample; (d) mixing the metered sample with the reagent in the analysis location; (e) allowing the reagent to form the reaction product in the sample; (f) after the mixing step, positioning the sample at the sensor in the analysis location using the pump; and (g) detecting the reaction product at the sensor.

As discussed in the January 30, 2009 Examiner Interview, Handique teaches an entirely different configuration and method in which gas, e.g., air, is pumped through gas intake 50 to move a microdroplet of length “L”. (See Handique FIG. 3A, and Col. 14, lines 35-44). While Handique discloses an overflow channel and overflow outlet (30), Handique teaches that the gas

displacing the microdroplet *bypasses* the overflow region (30). (Handique at FIGS. 3A, 3B, Col. 14, lines 40-44). Thus, Handique fails to teach or suggest pumping air *through an overflow chamber* to a metered sample, as recited in Claim 173. As a result, Applicants request that the Office withdraw the rejection of Claims 173 and 174 under 35 U.S.C. §102(b).

Conclusion

For the foregoing reasons, Applicants earnestly submit that the pending claims are in condition for allowance over the references of record, and a notice thereof is respectfully requested.

Should the Examiner have any questions regarding this response or the application in general, the Examiner is urged to contact the Applicants' attorney, Justin L. Krieger, by telephone at (202) 625-3858. All correspondence should continue to be directed to the address given below.

Respectfully submitted,

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